HEALTH FINANCE COMMISSION

Legislative Services Agency
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MEETING MINUTES[1]

Meeting Date:	**September 29, 2004**
Meeting Time:	**1:00 P.M.**
Meeting Place:	**State House, 200 W. Washington St., House Chamber**
Meeting City:	**Indianapolis, Indiana**
Meeting Number:	**3**

Members Present: **Rep. Charlie Brown, Chairperson; Rep. David Orentlicher; Rep. John Day; Rep. Carolene Mays; Rep. Scott Reske; Rep. Vaneta Becker; Rep. Robert Behning; Rep. Timothy Brown; Rep. Mary Kay Budak; Rep. David Frizzell; Sen. Patricia Miller, Vice-Chairperson; Sen. Billie Breaux; Sen. Vi Simpson; Sen. Timothy Skinner; Sen. Gregory Server; Sen. Gary Dillon; Sen. Beverly Gard; Sen. Connie Lawson; Sen. Marvin Riegsecker.**

Members Absent: **Rep. Craig Fry; Rep. Brian Hasler; Rep.Peggy Welch; Rep. Donald Lehe; Sen. Connie Sipes; Sen. Sue Landske.**

Chairman Rep. Charlie Brown called the third meeting of the Health Finance Commission to order at 1:10 P.M.

Bob Billings, Manager of Industry Affairs, Apotex Corp.

Mr. Billings described Apotex Corporation as the fastest growing generic pharmaceutical manufacturer in the country. The corporation has a national operations center located in

[1] Exhibits and other materials referenced in these minutes can be inspected and copied in the Legislative Information Center in Room 230 of the State House in Indianapolis, Indiana. Requests for copies may be mailed to the Legislative Information Center, Legislative Services Agency, 200 West Washington Street, Indianapolis, IN 46204-2789. A fee of $0.15 per page and mailing costs will be charged for copies. These minutes are also available on the Internet at the General Assembly homepage. The URL address of the General Assembly homepage is http://www.ai.org/legislative/. No fee is charged for viewing, downloading, or printing minutes from the Internet.

Indianapolis. He prefaced his remarks by specifying that he was commenting on the price variance issue from the perspective of a manufacturer of generic drug products.

Mr. Billings gave a brief description of the U.S. Food and Drug Administration's (FDA) process required to get a generic drug to market. New brand name pharmaceutical products require six major steps to receive FDA approval; generic drugs require five of these requirements (animal and human clinical trials are not required to be repeated for the generic equivalents). Generic equivalents must demonstrate to the FDA's satisfaction that the same amount of active ingredient in the generic reaches the peak therapeutic level in the blood and tapers off at the same rate as that experienced with the brand name drug. Generic drugs are required to match the variances that are allowed between manufacturing batches of the brand name drug. According to Mr. Billings, generic substitution should cause no different therapeutic response from the brand name drug. He stated that even for narrow therapeutic range drugs, the FDA claims the generic drugs are equivalent to the brand name drugs.

In response to the question of why generic drug prices vary so widely, Mr. Billings pointed out that brand name drugs are also priced differently at the retail level. He referred the Commission to the Health and Human Services homepage which provides a comparison list of prices by zip code. Mr. Billings stressed that from the manufacturer's perspective, generic drugs are sold in a commodity market. He also commented that if the manufacturer has exclusivity for the generic for 180 days as the result of being the first generic on the market after the brand name patent expires, they might price the generic according to the price of the brand name drug; about 20% less. However, once the period of exclusivity expires, the product price will drop rapidly. The price, he said, is determined by the marketplace.

Commission discussion followed regarding price reductions for product exclusivity, brand loyalty, and patent rights. In response to a question regarding whether generic drugs are truly equivalent in every way, Mr. Billings responded that for the average individual, the active ingredients in generic drugs will be therapeutically similar, although on an individual basis there may be differences in response. These differences would be expected to involve a small number of persons.

Chairman Brown announced that since there was a sufficient number of Commission members in the room to make a recommendation, he would hear the proposed legislation for the Commission's consideration next, deviating from the agenda.

PD 3310 Generic Drug Pricing by Pharmacies (Exhibit A)

PD 3310 would require a pharmacy to annually file proposed retail prices of generic legend drugs with the Board of Pharmacy. It would further require the Board to review and make a determination of approval or denials of proposed retail prices.

Chairman Charlie Brown announced that he would withdraw this draft from consideration in favor of a different version offered in PD 3337.

PD 3337 Generic Drug Pricing by Pharmacies (Exhibit B)

Ann Naughton, attorney to the Commission, gave a brief summary of the proposed legislation, which would require the Board of Pharmacy to annually develop a schedule of reasonable retail prices for generic legend drugs and review a random sample of pharmacies for compliance. In addition, it would require a pharmacy to annually file retail prices based on the schedule of reasonable prices with the Board of Pharmacy. There was discussion regarding who would determine the definition of a reasonable price, and whether any other professional boards had been empowered to regulate prices charged. Additional discussion followed regarding the

pricing of commodities on the market with the example of gasoline price variances being given and whether the Board of Pharmacy had the resources to address this task.

Two persons testified against the basic concept of the draft. Grant Monahan of the Indiana Retail Council commented that the Commission had heard an outstanding explanation by Professor Murawski of factors explaining why retail pharmacy prices vary. He said that this proposal constituted price fixing. There was Commission discussion regarding whether the approach taken in PD 3337 addressed the problem that it was trying to fix, how to make it known to drug purchasers that they need to shop for the best prices for generic drugs, and how to make that process as easy as possible. There was some discussion with regard to making comparative pricing information available in some format. Theresa Jolivette of the Indiana Chamber of Commerce testified that the Chamber rejects the concept of the government fixing retail prices.

Chairman Brown withdrew PD 3337 from consideration by the Commission.

PD 3345 Wholesale Drug Distributor Licensure (Exhibit C)

Chairman Brown requested Ann Naughton to describe the requirements of PD 3345, which expands the requirements that must be met by a wholesale drug distributor for eligibility for licensure in Indiana. The bill also specifies criminal acts related to wholesale drug distribution and legend drugs.

Chairman Brown withdrew PD 3345 from the Commission's consideration, explaining that it needed additional work.

PD 3302 Health Care Moratorium (Exhibit D)

PD 3302 would impose a two-year moratorium on the construction or addition of comprehensive care beds, ambulatory outpatient surgical centers, and hospitals. It would allow an exemption for continuing care retirement communities and certain health facilities, as well as certain exceptions to the moratorium on hospitals.

Chairman Brown withdrew PD 3302 from the Commission's consideration.

PD 3386 Public Hearings for Hospital Expansion or Construction (Exhibit E)

PD 3386 would require public notice and hearings before certain hospital construction or expansion projects may begin.

Rep. Becker commented that PD 3386 was intended to allow opportunity for public input to express concerns or support for hospital projects of a certain size. She added that the intent was to allow the public an opportunity to provide input, not to stop a project from proceeding. The Commission heard testimony from Tim Kennedy of the Indiana Hospital and Health Association (IHHA) that some public input into project development may already occur in zoning hearings. He added that without more detail, the IHHA was opposed to the draft.

The Commission voted 13-5 to support PD 3386.

PD 3394 Disclosure of Physician Interest in Health Care Entities (Exhibit F)

PD 3394 would require a physician to provide certain information to an individual before referring the individual to a health care entity in which the physician has a financial interest.

Rep. Becker explained PD 3394. There was discussion regarding whether the notice was required to be in writing and how the requirement would fit with the federal law that prohibits Medicare and Medicaid providers from referring to specified services in which they have a financial interest.

The Commission voted 17-0 to support PD 3394.

Progress Report on SEA 493-2003

Annette Biesecker, Legislative Director, FSSA (Exhibit G)

Ms. Biesecker prefaced her remarks by reporting that 1,100 individuals at imminent risk of nursing home placement had been diverted to home and community-based waiver services rather than being admitted to a nursing facility. Additionally, she stated that 140 individuals had been moved from nursing homes to a home-based setting. As she reviewed the material in Exhibit G, she commented that while some steps could not be implemented unilaterally, the requirements were implemented as far as FSSA had determined it was possible.

Ms. Biesecker reported that the Lewin Group had been engaged to analyze the fiscal impact of several provisions of SEA 493-2003 in order to answer fiscal feasibility questions from the Centers for Medicare and Medicaid Services (CMS). This report is expected to be available by the end of November.

Discussion followed regarding the need to build the service capacity of the home and community-based services (HCBS) available in the state, as well as the need for conversion of comprehensive care beds to other uses within the continuum of long-term care services. When asked what was the reason for the long delay in implementing the provisions of SEA 493-2003, Ms. Biesecker responded that the largest impediment has been the time requirements for the preparation of the financial analysis being done by the Lewin Group. There was additional discussion regarding the increase in the financial eligibility standards for home and community-based waiver applicants to 300% of SSI from 100% of SSI.

Final Report Draft (Exhibit H)

The Commission voted unanimously by voice vote, to approve the final report with the addition of the September 29, 2004, meeting testimony and the actions taken on the preliminary drafts.

John Cardwell, Indiana Homecare Taskforce (Exhibit I, J, K, & L)

Mr. Cardwell stated major provisions of SEA 493-2003 had not been implemented. He mentioned specifically adult foster care, assisted living, and the change in the home and community-based services waiver financial eligibility standard to 300% of SSI. He commented that the agency has implemented some of the easy provisions of the bill, but that in his opinion, the agency has deliberately drug its feet with regard to the full implementation of SEA 493-2003.

June Lyle, AARP

Ms. Lyle stated that AARP members overwhelmingly support the concept of in-home care. She also pointed out that the Lewin Group, hired by FSSA to perform the fiscal analysis of several provisions of SEA 493-2003, had just completed a study for the Commission on Government Efficiency. That study had a lead recommendation that the state should spend more on home and community-based services and less on nursing facilities. She also commented on the provisions of SEA 493-2003 that were not implemented and pointed out that in the case of

assisted living services and adult foster care, there were very few providers available to provide these services in the state. When asked what she thought was the major obstacle to the successful implementation of SEA 493-2003, she responded that, in her opinion, the administration had a negative attitude.

Paul Severance, United Senior Action (Exhibit M)

Mr. Severance said that with regard to the implementation of the 300% of SSI financial eligibility standard for the HCBS waiver, a former Secretary of FSSA had publically stated that 1,000 nursing facility diversions would provide sufficient savings to fund the increase in the financial eligibility standard. Once the agency approached this level of diversions, he commented that they then decided they needed to hire the Lewin Group for further analysis. He added that the agency has added many of the service provisions, such as for assisted living, but that they have done nothing to develop a provider base in undeveloped areas of the continuum of care. Mr. Severance said that some of the Area Agencies on Aging have told him that they are advising individuals that the one way to get HCBS waiver services is to physically move into a nursing facility in order to qualify for a prioritized conversion slot.

There was Commission discussion regarding the spending required to place an individual in a nursing facility as opposed to using home and community-based services.

Ms. Biesecker responded to some of the comments made. Chairman Brown requested that Ms. Biesecker arrange for a meeting to address the delays in implementation with Secretary Sullivan and the Budget Director for interested legislators and advocates.

Steve Albrecht, Indiana Health Care Association

Mr. Albrecht pointed out that nursing facilities are a necessary component of the long-term care continuum and that some of the dollar amounts suggested by earlier speakers as savings that could be achieved using HCBS were misleading. He suggested that, in total, dollars spent on long-term care needed to increase.

The meeting was adjourned at 3:55 P.M.